

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Mary Ann Hettich
Appl. No.: 10/780,510
Filed: February 16, 2004
For: Universal Chap-Style Compression Stocking

Confirmation No.: 1384
Group Art Unit: 3765
Examiner: Alissa L. Hoey

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests review of the final rejection in the above-identified application pursuant to the pilot program stated in the OG Notice of July 12, 2005. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Respectfully submitted,



Gregory J. Carlin
Registration No. 45,607

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111
LEGAL02/30015433v1

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REMARKS

The prior Office Actions fail to establish a *prima facie* case of obviousness. Please refer to the detailed arguments presented in the responses filed on February 28, 2006 and July 18, 2006 regarding the deficiencies in the obviousness rejection. The response to these arguments, as set forth in the Final Rejection of May 10, 2006, does not cure these deficiencies.

The Invention

The Applicant has developed a chap-styled therapeutic gradient compression stocking constructed such that it may be worn on either leg. The compression stocking includes a foot portion, a lower leg portion, an upper leg portion, a waist support and a hip portion extending between the waist support and the upper leg portion. The hip portion is formed around the lower waist of the patient and has two cutouts (24, 24'), as illustrated in one embodiment by Figure 1-4 of the present application, on generally opposing sides of the hip portion so that the stocking may be worn on either leg. The stocking of the illustrated embodiment is held in place by the waist support that includes a strap-engaging loop formed at the top of the hip portion, wherein a waist strap passes through the strap-engaging loop.

Claim Rejection – 35 U.S.C. § 103

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,440,665 to Russell, in view of U.S. Patent No. 3,975,929 to Fregeolle.

To establish a *prima facie* case of obviousness there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Additionally, the prior art references must teach or suggest all claim limitations. Furthermore, the teaching or suggestion to make the claimed invention must both be found in the prior art, not in applicant's disclosure. Accordingly, the Office Actions have failed to prove a *prima facie* case of obviousness because the references cited do not teach or suggest each and every claimed limitation nor demonstrate any suggestion to modify or combine the prior art in the manner suggested in the Office Actions.

The Prior Art Does Not Teach the Claimed Invention

Both Russell and Fregeolle fail to teach or suggest each and every element of independent Claim 1. Claim 1 recites a single gradient compression stocking including a hip portion having two cutout portions, such that the stocking may be worn on either leg and a waist

portion constructed to accommodate a fastener surrounding the patient's waist. For example, two cutout portions 24, 24' of the embodiment of Figures 1-4 of the present application are shown. The two cutout portions are on generally opposite sides of a single stocking, allowing the stocking to be switched from being worn on the right (Figure 1) to the left (Figure 2) leg.

Instead, Russell teaches a garment including a pair of attachable stockings 5, 6, as illustrated in Figure 1, wherein each individual stocking leg includes only one slit 21 (for the right-legged stocking), 22 (for the left-legged stocking) located such that when attached the single slit provides room for the crotch and upper thigh. As such, Russell does not teach a single stocking with two cutout portions.

Russell's stockings 5 and 6 can be united to form a single article of hosiery that is worn on both legs at the same time. However, in Russell a different stocking is specifically configured for the right and the left leg. Any attempt to place the left leg stocking 6 of Russell on the right leg would force the left-leg foot portion 11 to be reoriented backwards and left leg stocking 6 would not fit the right foot. It would be backwards. In addition, the right leg stocking 5 would not fit the left foot if worn on the left leg. The Office Actions are thus incorrectly attempting to equate a pair of stockings 5, 6 wherein each single stocking has a single slit 21, 22 configured for use on a single left or right leg, with a single gradient compression stocking with two cutouts such that the stocking may be worn on either leg.

Russell does suggest "easy interchangeability" of stockings from different pairs by turning one of them inside out. However, the compression stocking of Claim 1 of the present application has two cutout portions allowing it to be worn on either leg with the foot portion still fitting and without having to turn the stocking inside out. Turning a stocking inside out can expose the wearer to uncomfortable seams or welts meant to be on the outside of the stocking.

Furthermore, the stockings disclosed in the Russell reference do not include a waist portion surrounding the user's waist. As shown in Figure 2 of Russell, each individual stocking 5 or 6 has only enough waist portion 14 or 18 to extend half way around the wearer's waist. To extend the whole way around a waist, both stockings 5 and 6 must be combined with attachment of waist portion 14 or 18. Because Russell discloses only a dual-stockings system, there is no need for one of the stockings 5 or 6 to have its waist portion 14 or 18 extend entirely around the wearer's waist. A longer waist portion in Russell would result in the combined waist portions 14 and 18 being too loose to fit the wearer. As a result, Russell does not teach or suggest Claim 1 of the present application.

The Fregeolle reference discloses a gradient compression stocking having an enlarged upper section 10, a lower leg portion 11 and a foot 12, as shown in Figure 1. However, Fregeolle

fails to teach or suggest a hip portion, a waist portion, and two cutout portions on each side of a hip portion. Fregeolle describes the stocking as being only a “thigh length” elastic stocking in Fregeolle’s Claim 1. It is not designed to extend up all the way up to the hip. This coincides with Fregeolle’s illustration, in Figures 1 and 2, of the top edge of the upper section 10 and elastic band 20 of the stocking having the same height around its entire circumference. Thus, the enlarged upper section 10 would not be extendable up past the thigh onto the hip because its lack of any cutout portion would interfere with it being pulled up past the crotch.

Further, the elastic band 20 is sized to be the same circumference as the upper section 10, and therefore would not be large enough to extend around a waist that is much larger in diameter than a thigh. Fregeolle therefore also fails to disclose a waist portion for surrounding a wearer’s waist. Such an expanded length waist portion would not be needed since Fregeolle’s compression stocking is only meant to be a “thigh length” compression stocking. Expanding the length would render the elastic band 20 loose and ineffective at elastically holding the compression stocking to the thigh. As a result, Fregeolle does not teach or suggest Claim 1 of the present application.

Combining the Russell with Fregeolle would at best result in a compression stocking with a single slit for one hip and an elastic band not long enough to extend around a waist. Russell discloses only a single slit in each individual stocking and not two cutout portions. The waist portion disclosed by Russell and the elastic band disclosed by Fregeolle are both too short to extend around the wearer’s waist. None of the remaining cited references appears to overcome the failure of Russell and Fregeolle to teach or suggest Claim 1. The remaining Claims 2-7 depend from, and further patentably distinguish, Claim 1. The rejections of Claims 1-7 under 35 U.S.C. § 103(a) have therefore been overcome and the rejections should therefore be withdrawn.

***There Is No Suggestion or Motivation to Combine
Russell with Fregeolle***

The Office Actions do not offer any support that the prior art, including the knowledge generally available to one of ordinary skill in the art, provides any suggestion or motivation to modify the garment described in the Russell reference with the thigh length stocking of Fregeolle to achieve the currently claimed invention. Specifically, the obviousness rejection offers mere conclusions to indicate why one of ordinary skill in the art would seek to combine the cited references. Conclusory statements are insufficient to establish a prima facie case of obviousness. Furthermore, Russell, whether considered individually or in combination with Fregeolle, fails to provide any suggestion to modify the garment described in the Russell reference as suggested by

the Examiner. The only possible source for modifying Russell to include the recited compression gradient comes from Applicants' own disclosure, which is impermissible.

The Office Actions do not identify why a person of ordinary skill in the art would be incited to apply the gradient compression thigh length anti-embolism teachings of Fregeolle to the feminine hosiery teachings of Russell. Russell is concerned with providing feminine hosiery that covers the thigh and is adequately supported. On the other hand, Fregeolle is directed to providing a medical stocking for aiding blood flow and reducing clotting. At no point does Russell discuss or suggest the need or desirability of including a compression gradient stocking. Thus, there is no motivation to modify Russell or combine Russell with Fregeolle in the manner as currently claimed.

The Use of Hindsight is Improper

To date, the Office Actions has merely identified isolated elements from the references and combined them in an effort to reconstruct the claimed invention. What is missing is an explanation, supported by objective evidence of why one of ordinary skill in the art would be motivated to combine the cited references. Additionally, the mere fact that the prior art may be modified in the manner suggested does not make the modification obvious unless the prior art suggested the desirability of the modification. Clearly, the references themselves contain no specific teachings that would incite someone to combine the cited references in the manner asserted.

Furthermore, the absence of the necessary suggestion or motivation to combine the references requires a presumption that the combination of references selected to support the obviousness rejection is based on impermissible hindsight. *See In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). From the foregoing, it should be evident that hindsight reliance upon Applicant's own disclosure is the only conceivable basis why one would combine the cited references. This is not a proper basis for an obviousness rejection.

Conclusion

Applicant has clearly shown that the requirements for establishing a *prime facie* case of obviousness under 35 U.S.C. §103 have not been met. Accordingly, the obviousness rejection should be withdrawn.